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September 11, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

Re: In re Valsartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' position with respect to the topics on the agenda for the Case Management Conference with the Court on September 12.

1. Plaintiff Fact Sheets

The parties have agreed to the substance of the personal injury Plaintiff Fact Sheet, with the following three (3) exceptions:

(1) Lot No./Batch No.: In light of information that Plaintiffs are requesting in the Defendant Fact Sheet, Defendants would be greatly aided if Plaintiffs provided lot and batch number information, if known, for each of the valsartan-containing products identified in the personal injury PFS. The API and finished dose manufacturer Defendants are not in possession of lot and

batch number information for the valsartan-containing products provided to any specific Plaintiff. Until lot and batch numbers are identified for the product consumed by each Plaintiff, the manufacturer defendants will be unable to provide much of the information currently requested in the draft DFS.

While Defendants acknowledge that Plaintiffs may not be in possession of the Plaintiff-specific lot and batch number information in many instances, in some cases this information is readily available and is located on the prescription bottle label. In other instances the lot and batch information may be available from the recall notices provided to customers by their individual pharmacies. The lot and batch number information will be requested in the PFS with the qualifier "if known," and therefore will not hinder the timely completion of the PFS if such information is unavailable to any individual Plaintiff.

(2) List of Medical Conditions: The parties have met and conferred multiple times over the list of medical conditions to be identified within Paragraph V.F and have been unable to agree on a set list. The Court noted with respect to this section at the July 24, 2019 conference that "It seems . . . that this isn't a terrible burden for a plaintiff to answer yes or no." The Court further indicated that the Court "would lean in favor of disclosure, if there's a dispute." (CMC 5 Transcript at p. 36, ln. 9-22). Defendants have carefully reconsidered the list and have eliminated 30 conditions from the initial list in order to focus on the most relevant conditions. As such, we ask that the Court allow Defendants to ask about the following medical conditions which Plaintiffs oppose including in the PFS:

Condition	Yes	No	Unknown
Diagnosed and Treated Depression/Anxiety			
Diverticulitis			
Hypertension (High Blood Pressure)			
Hypotension (Low Blood Pressure)			
Intestinal obstruction			
Infectious disease such as H. pylori, encephalitis, and typhoid fever			
Malabsorption			
Obesity			
Persistent Constipation			
Persistent Diarrhea			
Persistent Nausea			
Persistent Vomiting			
Pulmonary Embolism/blood clot in lung			
Refractory celiac disease			
Small intestinal bacterial overgrowth			
Stroke of any type (hemorrhagic, ischemic, etc.)			
Transient Ischemic Attack (TIA)			
Unexpected weight loss			

(3) Litigation Funding: The parties await the Court's ruling on Defendants' proposed request for production of documents related to litigation funding. Briefing on this request was submitted on August 21, 2019.

Furthermore, in light of the progress the parties have made on the personal injury PFS, Defendants anticipate that the medical monitoring and economic loss fact sheets can be finalized shortly after the Court's rulings on the three items discussed above, followed by the finalization of the third party payor PFS which will require inquiry into new areas.

2. Process for Dismissal of Peripheral Defendants

The parties have reached an agreement in principle on the language of a Stipulated Conditional Order of Dismissal Without Prejudice and Commensurate Tolling of Statute of Limitations ("Dismissal Order"), which provides for the without prejudice dismissal of certain peripheral defendants, namely re-packagers and two retailers. (The parties were unable to reach an agreement regarding dismissal of the larger retailer defendants, among others, at this time.) The parties are conducting a final review of the Dismissal Order and an implementation order. The parties expect to be able to submit the orders to the Court for filing before September 25, 2019, the date of the next case management conference. The current form of implementation order preserves the rights of the large retailers and others to revisit a without prejudice dismissal at a later time.

3. ANDA Productions

The Defendants who previously produced ANDA files pursuant to the Court's Core Discovery Order are preparing to produce the ANDA files in eCTD format, to the extent available, by September 16, 2019, as directed by Case Management Order No. 12 (Dkt. 185).

For Teva's older ANDA files which were submitted to the FDA in the Common Technical Document ("CTD") format which predated eCTD, Plaintiffs have agreed to accept production of such files in CTD format as they were originally submitted to the FDA. Separately, Mylan has reached out to Plaintiffs' counsel to address certain issues in advance of this production. It is anticipated that those issues—largely technical in nature—can be resolved without Court intervention.

4. JPML Petition to Expand the MDL

On August 21, 2019, Plaintiffs filed a Motion to Transfer and Expand the Scope of MDL 2875 with the Judicial Panel on Multidistrict Litigation ("JPML"). Specifically, Plaintiffs seek to expand this MDL to include "all federal cases concerning Angiotensin Receptor Blockers ("ARB's") contaminated with carcinogenic contaminants."

A number of Defendants plan to oppose Plaintiffs' motion. The Parties expect that the motion will be heard at the JPML's December 5, 2019 hearing session.

5. Defendant Fact Sheet

Pursuant to the Court's guidance at the August 14 case management conference and Case Management Order Nos. 10 and 12 (Dkt. 141, 185), Defendants are reorganizing the draft Defendant Fact Sheet previously provided by Plaintiffs to categorize the information requests questions based on supply chain level, i.e., API manufacturer or finished dose manufacturer. Defendants will circulate this draft to Plaintiffs this week and expect to be able to finalize the Defendant Fact Sheet by the time of the September 25 case management conference.

6. Service of Process Update

It is Defendants' understanding that Plaintiffs have sent or will be sending waiver of service of summons forms to all known defense counsel of record. Defendants also understand that Plaintiffs plan to serve summons on any defendants that do not have counsel of record in at least one case in the MDL.

7. Addition of Mylan, NV to Short Form Complaint

As the Court is well aware, the Short Form Complaint was the product of extensive negotiations over a number of months. The final form was approved by counsel and entered by the Court. It names two "Mylan" entities: (i) Mylan Laboratories Ltd. (MLL), a manufacturer of valsartan API; and (ii) Mylan Pharmaceuticals Inc. (MPI), a manufacturer of finished-dose valsartan-containing medications.

Mylan N.V. is a holding company that came into existence in or about 2015. It does not play and never has played any role in the manufacture, distribution, or sale of valsartan. While it is true that both MLL and MPI are indirectly wholly owned subsidiaries of Mylan N.V., "it is deeply ingrained in our economic and legal systems that a parent corporation is not liable for the acts of its subsidiaries. Liability will not be imposed on the parent corporation merely because of its ownership of the subsidiary[.]" *Portfolio Fin. Servicing Co. ex rel. Jacom Computer Servs. v. Sharemax.com, Inc.*, 334 F. Supp. 2d 620, 626 (D.N.J. 2004) (citations and internal punctuation omitted).

Accordingly, whereas Mylan N.V. was included on early drafts of the Short Form Complaint, it was removed—without objection from Plaintiffs—during the meet-and-confer process. Now, after the Short Form Complaint has been finalized, approved, entered, and utilized,

Plaintiffs have requested to scrap it in order to reinsert Mylan N.V. under the category of "API Manufacturer" with a notation that it is the parent of MLL. But, as noted, Mylan N.V. is *not* an API manufacturer, nor is it a finished-dose manufacturer or distributor or any other role in the chain of distribution of valsartan-containing medications. Simply put, there is no basis for liability against Mylan N.V., and Plaintiffs have not pointed to anything in the thousands of pages of core discovery documents produced thus far to suggest otherwise. As such, there is no basis to list this entity in the Short Form Complaint and Plaintiffs' request to do so should be denied

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
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